PROTECTED TAVR

RANDOMIZOVANÁ STUDIE SROVNÁVAJÍCÍ RŮZNÉ STRATEGIE UZÁVĚRU PUNKCE TEPNY O VELKÉM PRŮMĚRU

MARTIN MATES, NEMOCNICE NA HOMOLCE, PRAHA

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Cerebral Embolic Protection during Transcatheter Aortic-Valve Replacement

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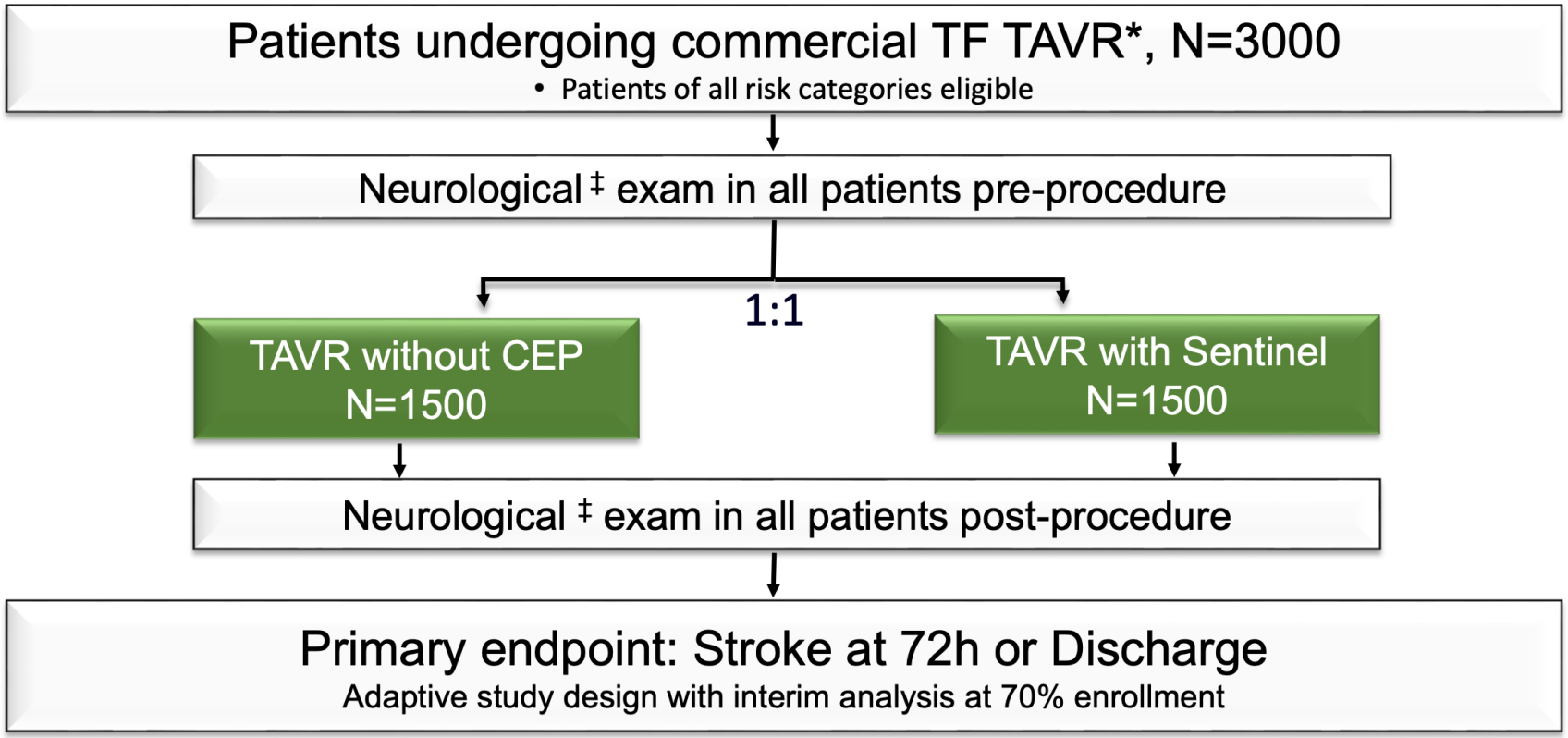
ABSTRACT

PROTECTED TAVR:

Stroke PROTECTion with SEntinel During Transcatheter Aortic Valve Replacement

Study Chair: Marty Leon
Principal Investigators: Global PI-Samir Kapadia, MD;
Co-PI-Axel Linke, MD



ZÁKLADNÍ CHARAKTERISTIKA SOUBORU

Table 1. Demographic and Clinical Characteristics of the Patients at Baseline and Procedural Characteristics.*

Characteristic	CEP (N=1501)	Control (N=1499)
Demographic		
Age — yr	78.9±8.0	78.9±7.8
Female sex — no. (%)	631 (42.0)	566 (37.8)
Clinical		
STS surgical risk score — %†	3.3±2.7	3.4±2.8
Surgical risk according to heart team — no. (%)		
High or extreme risk	457 (30.4)	456 (30.4)
Intermediate risk	499 (33.2)	512 (34.2)
Low risk	545 (36.3)	531 (35.4)

PRIMÁRNÍ ENDPOINT

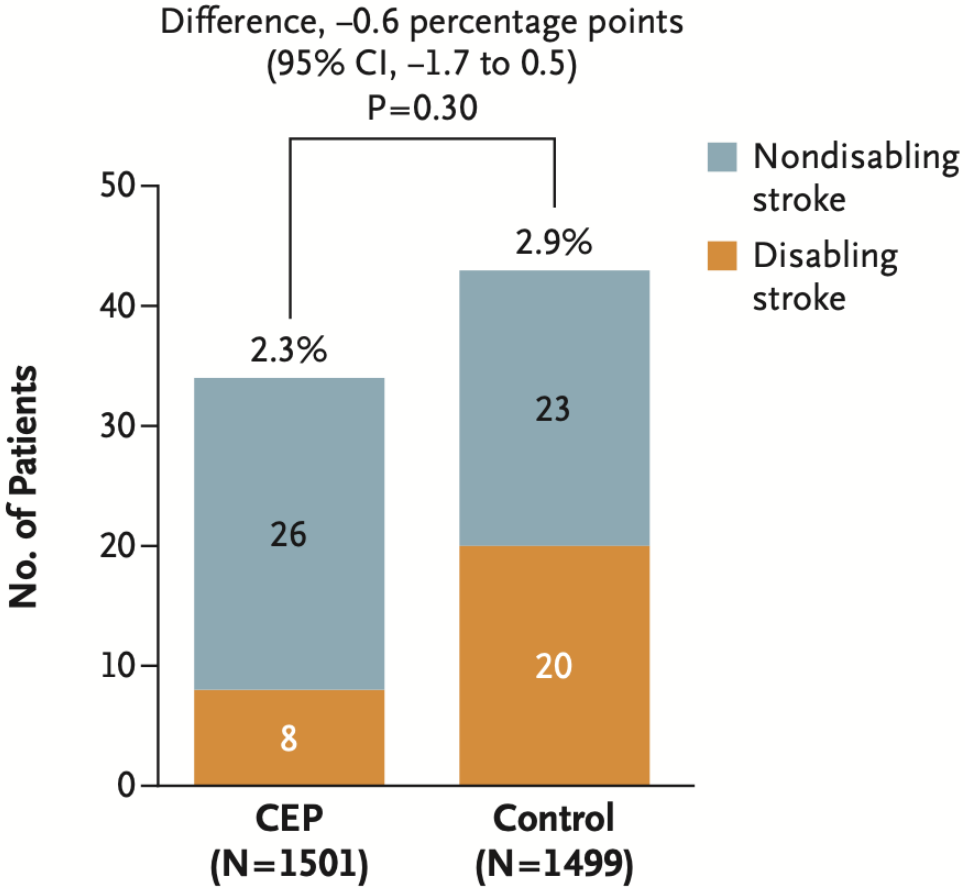


Figure 2. Stroke within 72 Hours after TAVR or before Discharge (Primary End Point) in the Intention-to-Treat Population.

Stroke within 72 hours after TAVR or before discharge (whichever came first) was adjudicated by an independent clinical events committee.

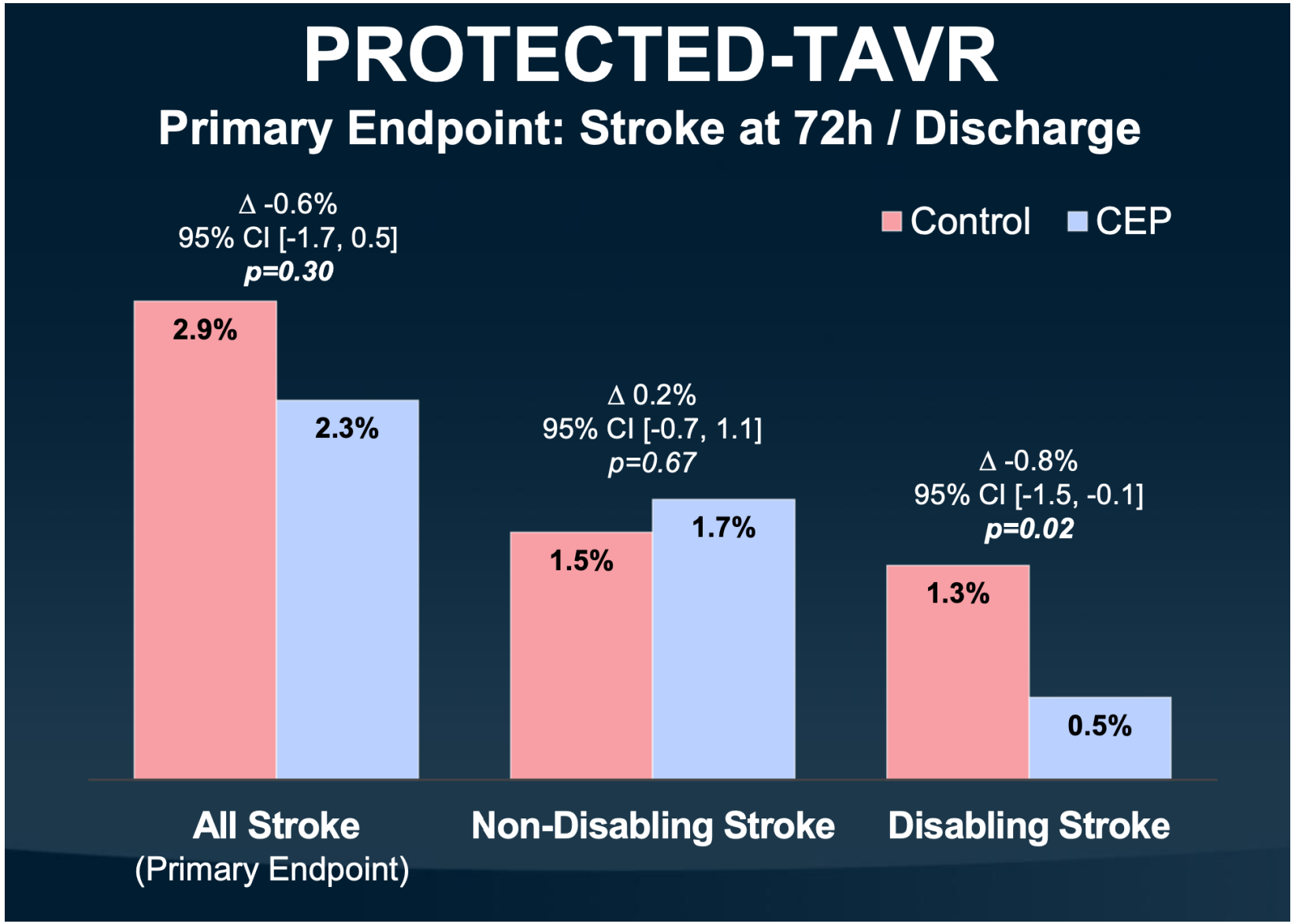
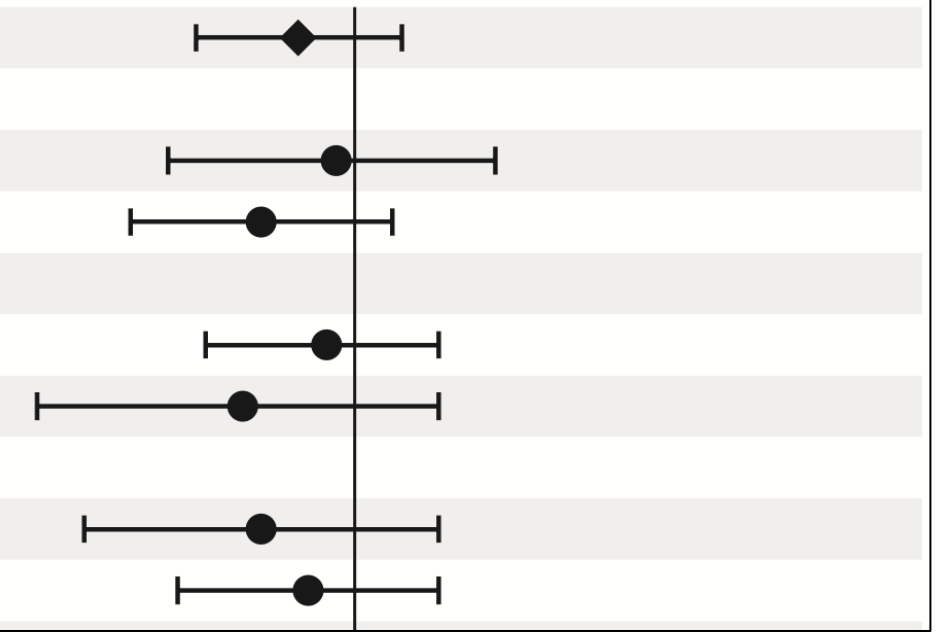

PROTECTED-TAVR
Primary Endpoint: Stroke at 72h / Discharge
Control
CEP
Δ -0.6%
95% CI [-1.7, 0.5]
p=0.30
2.9%
2.3%
Δ 0.2%
95% CI [-0.7, 1.1]
p=0.67
1.5%
1.7%
Δ -0.8%
95% CI [-1.5, -0.1]
p=0.02
1.3%
0.5%
All Stroke
(Primary Endpoint)
Non-Disabling Stroke
Disabling Stroke

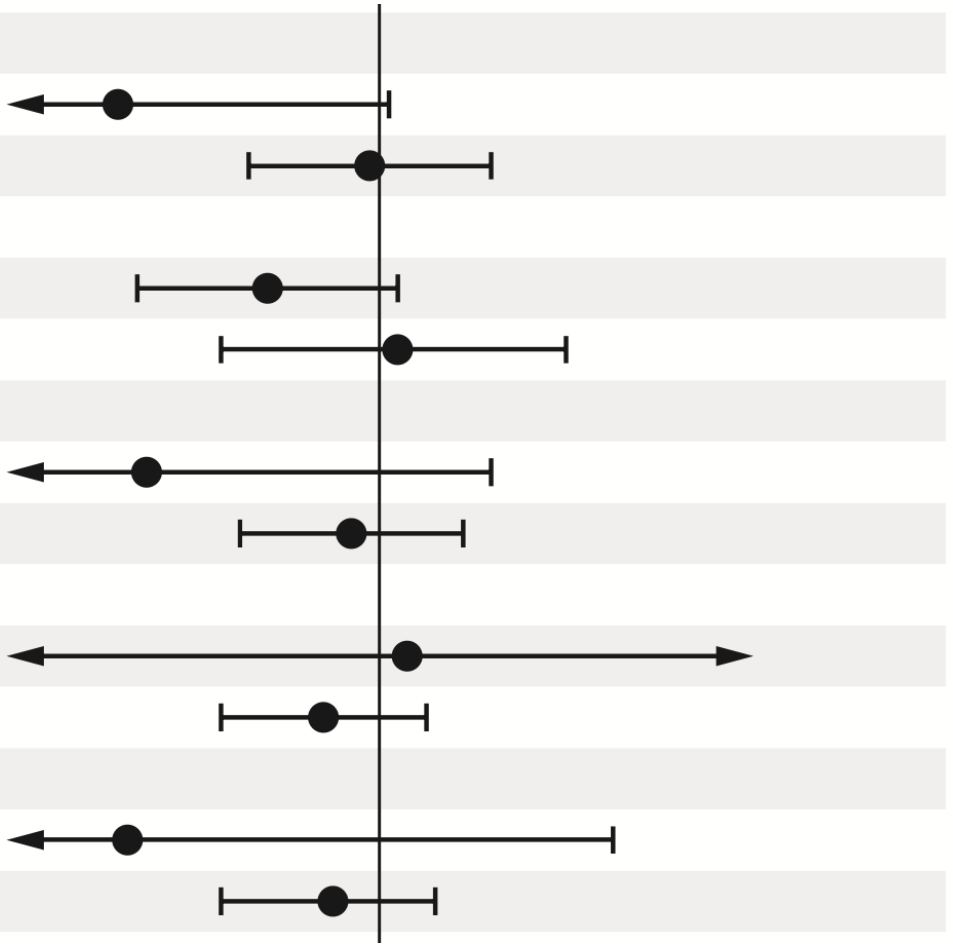
Table 2. Clinical and Neurologic Outcomes within 72 Hours after TAVR or before Discharge.*

Outcome	CEP (N=1501)	Control (N=1499)	Difference (95% CI)†
Clinical			
Primary end point: stroke — no. (%)	34 (2.3)	43 (2.9)	–0.6 (–1.7 to 0.5)
Disabling	8 (0.5)	20 (1.3)	–0.8 (–1.5 to –0.1)
Ischemic	6 (0.4)	17 (1.1)	–0.7 (–1.4 to –0.1)
Hemorrhagic	2 (0.1)	3 (0.2)	–0.1 (–0.4 to 0.2)
Nondisabling	26 (1.7)	23 (1.5)	0.2 (–0.7 to 1.1)
Ischemic	26 (1.7)	23 (1.5)	0.2 (–0.7 to 1.1)
Hemorrhagic	0	0	0

Subgroup	CEP	Control	Difference (95% CI)
	no. of patients with event/total no. of patients (%)		
All patients	34/1501 (2.3)	43/1499 (2.9)	
Age			
≥80 yr	23/760 (3.0)	25/771 (3.2)	
<80 yr	11/741 (1.5)	18/728 (2.5)	
Sex			
Male	15/870 (1.7)	19/933 (2.0)	
Female	19/631 (3.0)	24/566 (4.2)	
STS surgical risk score			
≥3%	17/658 (2.6)	22/620 (3.5)	
<3%	16/823 (1.9)	21/862 (2.4)	



Aortic-valve calcification			
None or mild	3/241 (1.2)	9/223 (4.0)	
Moderate or greater	30/1192 (2.5)	32/1218 (2.6)	
History of coronary artery disease			
Yes	15/850 (1.8)	26/880 (3.0)	
No	19/643 (3.0)	17/613 (2.8)	
History of peripheral vascular disease			
Yes	3/165 (1.8)	7/162 (4.3)	
No	31/1319 (2.4)	35/1319 (2.7)	
Previous cerebrovascular event			
Yes	5/114 (4.4)	5/122 (4.1)	
No	29/1382 (2.1)	37/1369 (2.7)	
Use of valve-in-valve procedure			
Yes	0/56	1/37 (3.0)	
No	34/1445 (2.4)	42/1462 (2.9)	

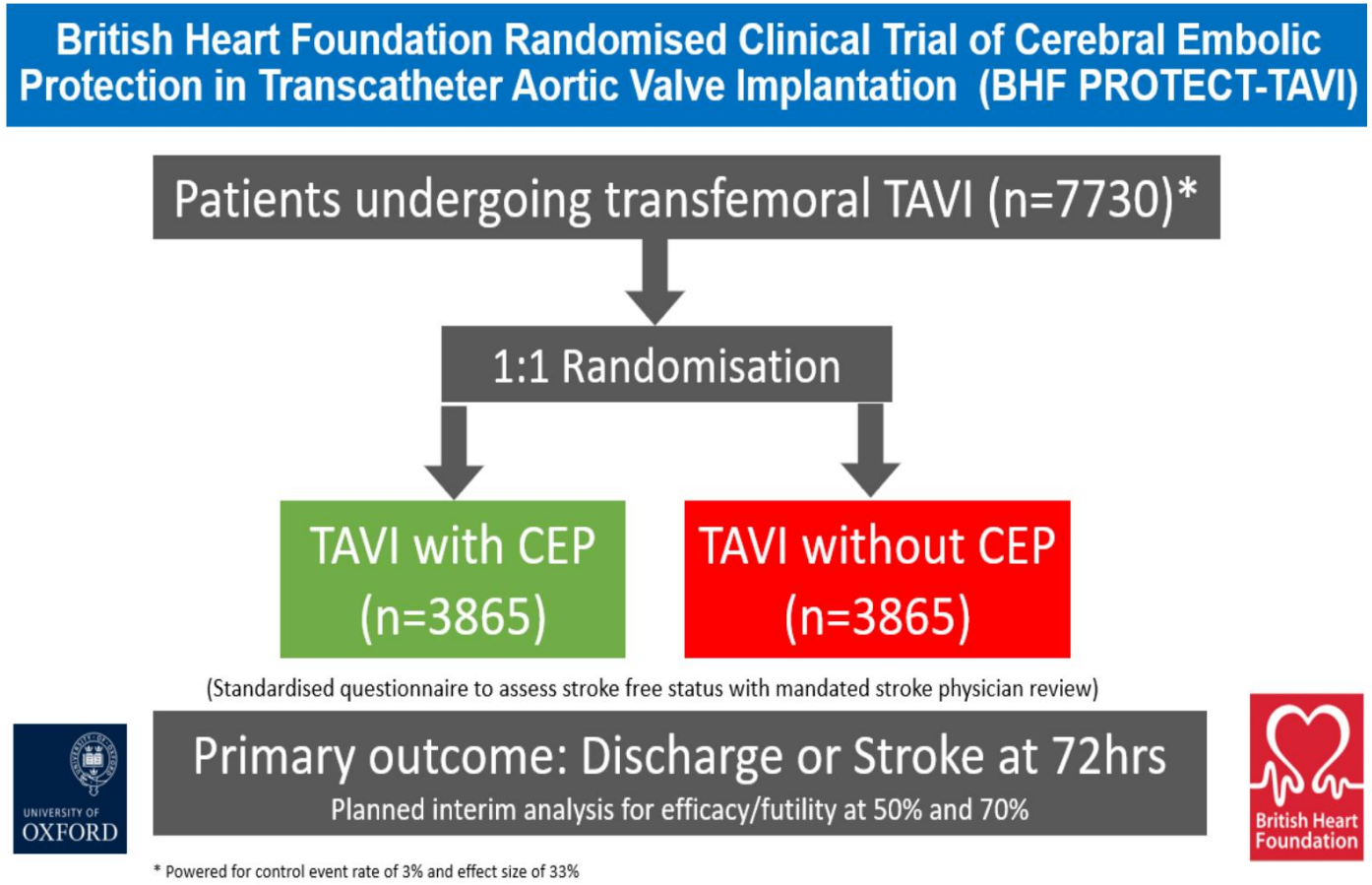


ZÁVĚR

Among patients with aortic stenosis undergoing transfemoral TAVR, the use of CEP did not have a significant effect on the incidence of periprocedural stroke, but on the basis of the 95% confidence interval around this outcome, the results may not rule out a benefit of CEP during TAVR.

BHF PROTECT-TAVI

Chief Investigator: Professor Rajesh Kharbanda



- Enrollment (N=2221)
  (as of May 15, 2022)
- 26 sites enrolling